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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/576,623 | 05/23/2000 | John G. Carman | T4088.Cont | 2724 |

20450 7590 11/29/2002

ALAN J. HOWARTH
P.O. BOX 1909
SANDY, UT 84091-1909

EXAMINER

KUBELIK, ANNE R

| ART UNIT | PAPER NUMBER |
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1638

DATE MAILED: 11/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|-----------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/576,623 | CARMAN, JOHN G. | |
| | Examiner | Art Unit | |
| | Anne R. Kubelik | 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 10, 13-15, 19-22 and 24-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-12, 16-18, 23 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The amendments to claims 1-3, 5-7, 9, 17-18 and 23, and the addition of claims 35-37 requested in Paper No. 14, filed 13 September, 2002, have been entered. Claims 1-37 are pending. Claims 10, 13-15, 19-22 and 24-33 are withdrawn from consideration as being drawn to non-elected inventions. new claims 36-37 belong to Group I. Claims 1-9, 11-12, 16-18, 23 and 34-37 are examined to the extent they read on a method of breeding for diploid hybrid plant lines exhibiting apomixes.
2. Applicant is required to delete non-elected material from the claims 1-9, 11-12, 16-18, 23 and 34-37 and to delete non-elected claims.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The disclosure is objected to because of the following informality: The line across the page on line 10, pg 62, will potentially cause problems during printing and should be deleted.
5. The draftsman has approved the drawings submitted 16 September 2002.

Priority

6. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994).

As stated in the prior Office action, provisional application 60/037,211 fails to provide adequate support under 35 USC 112 for claims 1-9, 11-12, 16-18, 23 and 34-37 of the instant application. Claims 1-9, 11-12, 16-18, 23 and 34-37 are methods that have the critical and essential method step of identifying starting plant materials. The disclosure of '211 fails to disclose the step of identification of starting materials by their different flowering response, a critical and essential step in the methods as claimed.

Applicant's arguments filed 13 September, 2002, have been fully considered but they are not persuasive. Applicant urges that the provisional application stated, "across genome heterogeneity ... at the time of reproductive development is responsible for apomixes" and "'only interactions between gene cassettes from specifically-divergent genomes will cause an appropriate degree of asynchrony and induce apomixis". Applicant further urges that '211 states, "the asynchrony hypothesis predicts that ... the progeny of amphiploids from appropriately selected parents (based on ... cytologically observable temporal differences in the timing of female development) will be apomictic". Applicant points to pages of '211 that were latter published and summarizes them as teaching data that supports the duplicate gene asynchrony explanation for apomixis, describes cytological techniques useful in classifying stages of female floral development, and that teaches that diplospory may be caused by the expression of embryo sac signals for one genome precociously expressed with megasporogenesis signals from another. Applicant urges that pg 106-107 of '211 provide claims that describe a method of developing apomictic plants wherein the first step is identifying parent plants that exhibit differences in the timing of female reproductive development (response pg 10-14).

This is not found persuasive because '211 provides no support for differentiating the lines based on their flowering responses to photoperiods or for selecting plants based on their day-length response.

Applicant also urges that the papers that were later published, including Carman, 1997, cannot be used as prior art to the instant application because the entire substance of these references was disclosed in '211 (response pg 14). Examiner notes that none of these publications are being used as prior art against any claims in the instant application.

Claim Objections

7. Claims 5-6, 8 and 18 are objected to because of the following informalities:

In claim 5, "and" at the end of line 4, should be deleted.

In claim 6, the underlined "and" in line 5 should be deleted, and in claim 18, it should be deleted from part (c).

In claim 8, an article is missing before "nongametophytic" in line 1.

In claim 18, part (d)(i), the underlined comma should be replaced with a non-underlined one.

Claim Rejections - 35 USC § 112

8. Claims 1-9, 11-12, 16-18, 23 and 34-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the

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Office action mailed 8 May, 2002, as applied to claims 1-9, 11-12, 16-18, 23 and 34. Applicant's arguments filed 13 September, 2002, have been fully considered but they are not persuasive.

The claims are broadly drawn to a method of producing apomictic plants from sexual plants by hybridizing any two sets of plants lines, wherein the plants lines differ in their flowering responses to photoperiods and their start times and durations of female or seed developmental stages.

The instant specification provides guidance for identifying species of *Antennaria* (x=14) and *Tripsacum* (x=18) with broad geographic distributions and varying photoperiod responses and embryology and prophetic collection of isolates of those species from the wild (pg 45-51); identification of the effects of different photoperiods on floral development by analysis of variance of data on bud formation, archesporium formation, megasporogenesis, megagametogenesis and flowering times after removal from a vernalization chamber obtained by cytological and morphological means of unidentified *Tripsacum* species (pg 51-57); prophetically increasing divergence in flowering response to different photoperiods and female developmental schedules by intercrossing lines that have similar day lengths (pg 58-59); prophetically obtaining three or more lines of the same species or closely related species with long day lengths and early archesporium development or short day lengths and late archesporium development and selecting lines that form a continuum with regard to day length, selecting one set of lines such that initiation of embryo sac development occurs at the same time as female meiotic prophase starts in the other set of lines, and producing amphiploids by colchicine induction or repeated production of B_{III} hybrids (pg 60-62); and prophetic production of apomictic plants (pg 62).

The instant specification fails to provide guidance for methods of hybridizing any two "related" plant species; as all plants are related to some extent, the method, as claimed, is drawn to crossing any plant species.

The specification also fails to provide guidance for determination of which degree of difference in flowering responses to photoperiods and start times and durations of female or seed developmental stages is needed between the two lines.

The Declaration of John G Carman, filed 15 February, 2001, has been considered. It does not demonstrate that the specification is enabling for the instantly claimed invention. It teaches that the beginning of embryo sac formation was considered differently in *Sorghum* and *Tripsacum* than it was in *Antennaria* (pg 4-5); the specification does not teach that this was necessary. The *Sorghum* crosses in Table 4 show no correlation between differences in photoperiod and the start time and duration of female or seed development and production of apomictic progeny; for example, crosses with plants with no differences in photoperiod produced proportions of apomictic progeny similar to plants with a difference (e.g., hybrids 101 and 76 or 113). The Declaration also teaches that high MS and low EES-MS values are required to produce apomictic progeny (pg 22, paragraph 2); the specification does not teach that this is necessary. The Declaration does not teach that apomictic plants could be produced by crossing plants that are not of the same genus.

Garcia et al (2000, Maize Genet. Coop. Newsletter 74:40-41) teach that *Tripsacum* and *Antennaria* have the same type of apomixis, one in which meiosis is lacking (pg 40, right column, 1st paragraph of the article). The specification fails to provide evidence that the claimed method of producing apomixis would work in plants that have different types of apomixis.

Production of apomictic plants by crossing plants with different photoperiods, different start times of flowering and different durations of female developmental stages is unpredictable. Purnheiser (1993, *Cereal Res. Comm.* 21:175-179) teaches that crossing wheat plants with different photoperiods, different start times of flowering and different durations of female developmental stages does not produce apomictic plants, thus showing the instant method is not enabled (pg 176, paragraph 2, and pg 177, paragraph 5). Dung et al (1998, *Theor. Appl. Genet.* 97:714-720) teach the crossing of rice plants with widely different flowering responses to photoperiods and wide differences in the start times and durations of female or seed developmental stages; no apomictic plants were produced (pg 715, left column, paragraph 2, to pg 716, left column, paragraph 2).

Peel et al (1997, *Crop Sci.* 37:717-723) teach that in wheat, induction of apomixis will require the transfer of alien gene cassettes that confer reproductive asynchrony (abstract). The instant specification does not teach this requirement.

The art teaches that apomixis is caused by a single dominant locus, (see, *e.g.*, Koltunow et al, 19995, *Plant Physiol.* 108:1345-1352, see pg 1349, right column, paragraph 1; 1350, left column, paragraph 4). The instant specification does not teach how identification of plant photoperiod, and the start times and durations of female and seed development are related to that locus.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate methods for producing apomictic plants from sexual plants by hybridizing any two sets of plants

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lines, wherein the plants lines differ in their flowering responses to photoperiods and their start times and durations of female or seed developmental stages.

Applicant urges that for the first time in history, using the instant invention, apomixis can be intentionally obtained and because this is pioneering technology, it is being broadly claimed. Applicant urges that plant breeding is a well-known technology and its techniques are routine, and the essential difference between the instant invention and the prior art is the selection of parent plants. Applicant urges that the inventor synthesized information from many interrelated disciplines to make the invention and the invention was not obvious to others in the art (response pg 28-30). This is not found persuasive. None of these arguments are relevant to whether the specification is enablement for the instantly claimed invention. A broadly claimed invention requires it be broadly enabled.

Applicant urges that conventional wisdom at the time of filing held that apomixis is caused by only a gene or two and that the prior art attempts to transform those genes into sexual lines by breeding with facultative apomictic plants. Applicant urges that the instant invention is based on asynchrony of many duplicate genes required for female or seed development and that plant breeding is known in the art (response pg 31). This is not found persuasive because the specification fails to provide guidance for crossing any two plants.

Applicant urges that the level of skill of one in the art is relatively high. Applicant urges that one of skill in the art would know that a realistic likelihood of obtaining viable progeny is possible when crossing plants within the same species, genus or family and would also know that interfamily crosses are unlikely to yield viable progeny. Applicant urges that Salibury et al (not sent) teaches how to recognize differences in flowering responses in plants, and the specification

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teaches that these include induction of flowering and maturation of buds into flowers and teaches methods for quantifying these. Applicant urges that one of ordinary skill in the art would also know all the steps required for hybridizing selected plant lines by plant breeding (response pg 31-32). This is not found persuasive. Because "related plant species" is not defined in the specification, and because there is no set meaning for the term in the art, the claims are drawn to crosses between any two plants. The specification does not provide guidance for crossing any two plants. Salibury could not be considered because it was not sent.

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Applicant urges that Purnheiser, cited in the prior Office action, teaches techniques that can be used to perform the crosses of the instant method (response pg 34-36). This is not found persuasive. Purnheiser teaches that crossing wheat plants with different photoperiods, different start times of flowering and different durations of female developmental stages does not produce apomictic plants, thus showing the instant method is not enabled (pg 176, paragraph 2, and pg 177, paragraph 5).

Applicant urges that each of Bates and Garcia et al, cited in the prior Office action, teach the difficulties in and solutions for accomplishing interspecific and intergeneric hybridizations in plants. Applicant also cites Torabinejad et al and Liu et al to support arguments but did not send these articles (response pg 36-37). This is not found persuasive. Bates et al teach that crosses between the "similar species", maize and sorghum could not be effectively accomplished (pg 5-

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3B). With respect to Garcia et al, see *In re Glass*, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification. Torabinejad et al and Liu et al could be considered because they were not sent.

Applicant urges that wide crosses are not necessary to practice the instant invention. Applicant urges that DeWet et al, cited in the prior Office action, wanted to determine if apomixis could be transferred from *Tripsacum* to maize and that they recovered triploid progeny because of an elimination of maize chromosomes, which was caused by sexual meiosis, not apomeiotic processes (response pg 37-38). This is not found persuasive. The instant application relies of sexual processes for the production of apomixis. Thus, Applicant's arguments with respect to Dewet et al are not on point. De Wet et al show that the production of triploids means that breeding for apomixis by sexual hybridization is unpredictable.

Applicant agrees with the prior Office action that Hovin et al, Hanna et al, and Holm et al, cited in the prior Office action, teach that screening of apomictic plants for percentage of apomictic progeny is unpredictable, but urges that the techniques required to accurately do that screen are well-known in the art. Applicant urges that the screening method Hovin et al teaches must be used was used in the *Sorghum* lines in the Declaration. Applicant also cites Leblanc et al and Asker et al to support arguments but did not send these articles. (response pg 38-40). This is not found persuasive. Hovin et al, Hanna et al, and Holm et al do teach that screening of apomictic plants for percentage of apomictic progeny is unpredictable. The specification does not teach how to overcome this unpredictability. The specification also does not teach that

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screening method required for Sorghum. Leblanc et al and Asker et al could be considered because they were not sent.

Applicant urges that determination of whether a progeny is apomictic is secondary to practicing the methods of the instant specification (response pg 41). This is not found persuasive. The methods of the instant application require selection of apomictic progeny; thus determination of whether a progeny is apomictic is integral to the instant invention - it is the last step of the instantly claimed method. The specification does not teach the critical screening methods for this determination.

Applicant urges that while each of Hanna et al, Carman, and Bashaw et al, cited in the prior Office action, teach that multiple genes may be involved in apomixis, those who believe a single gene is responsible for apomixis argue that multiple genes would not be evolutionarily feasible (Applicant here cites Asker et al, Mogie et al and Savidan et al, but did not send them). (response pg 41-43). This is not found persuasive. Applicant's arguments with respect to the disagreement in the art regarding the number of genes involved in apomixis could not be considered because the relevant references (Asker et al, Mogie et al and Savidan et al) were not sent.

Applicant also urges that Carman is not a proper reference against the instant application because the provisional application contains the entire article (response pg 41-42). This is not found persuasive. Carman is not being used as prior art against the instant application. Any article, by the inventor or not, and whether published prior to or after the priority date of an application, can be used as a reference in an enablement rejection. The presence of the Carman article in the provisional application means that it could not be used in a 37 USC 102 or 103 rejection, but has no relevance on its use in a 37 USC 112 rejection.

Applicant urges that the specification provides a thorough explanation of how to practice the duplicate-gene asynchrony approach to making apomictic plants and explains why the theories of the prior art are deficient. Applicant urges that Example 3 is a working example of quantifying effects of different photoperiods on flowering and example 5 is a working example of quantifying divergence in female developmental schedules. Applicant also urges that the Declaration of John G. Carman filed 9 February, 2001, discloses that apomixis was obtained in *Antennaria*, *Sorghum* and *Tripsacum* using the instant methods (response pg 45-47).

This is not found persuasive for the reasons indicated above.

Applicant urges that some experimentation would likely be necessary with each new species or genus used, but that this experimentation would be routine (response pg 47-48).

This is not found persuasive because of the lack of guidance for the critical differences required to achieve the production of apomictic progeny, as discussed above.

9. Claims 1-9, 11-12, 16-18, 23 and 34-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection different from that set forth in the Office action mailed 8 May, 2002, as applied to claims 1-9, 11-12, 16-18, 23 and 34.

Claims 1, 17-18 and 34-37 are indefinite in their recitation of "from sexual plants", "from sexual plants" or "from ... sexual plants" in line 2 or lines 1-2. It is not clear if this means plants that normally only reproduce sexually or if facultative apomictic plants are intended to be included. Additionally, as environment causes apospory in many plants (see, e.g., Evans et al,

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abstract, and Hussey et al, pg 144, left column, paragraph 3), it is not clear if those plants are included or excluded from this method - are they, for example, included when they are sexual but not when they are apomictic, or are they always included because they are sexual under some circumstances?

Claims 1, 17-18 and 35-37 are indefinite in their recitation of "that are differentiated". It is not clear what the phrase is intended to modify. By position in the claims, it modifies "related plant species". It is thus unclear what, if any, differences there are among the plants of the plant species.

Claims 2-3 lack antecedent basis for the limitation "the differentiation in flowering responses".

Claims 2-3 are indefinite in their recitation of "the differentiation in flowering responses ... day neutral plants". It makes no sense to say, for example, that a differentiation occurs within short-day plants. A plant is not a differentiation. It is also unclear what it means for a differentiation to occur within a plant or across a plant. What are "within" and "across" intended to mean here? Claim 18 is similarly indefinite for its recitation of "divergence occurs ... day-neutral plants" in part (d)(i).

Claim 4 is indefinite in its recitation of "differentiation of flowering responses breeding". This appears to be another method step, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 5-7 are indefinite in their recitation of "differentiation in start times and durations". First, the phrase lacks an antecedent basis in claim 1. Additionally, it makes no sense to say, for example, that a differentiation occurs within archespore formation. It is also unclear, in claims 5-6, what it means for a differentiation to occur within or across each of the members of the group. What are "within" and "across" intended to mean here?

Claim 7 is indefinite in its recitation of "differentiation in start times a breeding step". This appears to be another method step, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 9 is indefinite in its recitation of "lines comprise genomes from each set of delineated lines". Is this intended to mean that the hybrid lines comprise the entire genomes from all the delineated lines?

Claim 11 lacks antecedent basis for the limitation "the genetic material" in line 1. It is also unclear whose genetic material is being referred to.

Claim 11 is indefinite in its recitation of "that confer apomixis." It is not clear what the phrase is intended to modify. By position in the claims, it modifies "lines", but this makes no sense. Additionally, it is unclear what degrees of asynchrony are considered appropriate or what character is asynchronous.

Claims 12 and 16 lack antecedent basis for the limitation "said selected hybrid lines".

Claim 17 lacks antecedent basis for the limitation "the hybridization" in part (e).

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10. Claims 1-9, 11-12, 16-18, 23 and 34-37 are free of the prior art, given the failure of the prior art to teach or suggest a method of producing apomictic plants from sexual plants by hybridizing any two sets of plants lines, wherein the plants lines differ in their flowering responses to photoperiods and their start times and durations of female or seed developmental stages. and given the lack of enablement discussed above.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
November 26, 2002



AMY J. NELSON, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600